

## **REMARKS**

### **Status of the Claims**

Claims 1, 10, 12, 13, 15-20, 23 and 24 are currently pending in the application. Claims 1, 4, 5, 10, 12, 13 and 15-22 stand rejected. Claim 1 has been amended as set forth herein. Claims 4, 5, 21 and 22 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. New claims 23 and 24 have been added herein. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is supported by the specification at, for instance, paragraph [0063] of U.S. Patent Application Publication No. 2004/0063122, published on April 1, 2004, corresponding to the present specification at page 11, line 35 to page 12, line 14. New claims 23 and 24 are supported in the specification at, for instance, Example 6, page 10, lines 21-24 and especially page 11, lines 13-23. Reconsideration is respectfully requested.

### **Changes to the Specification**

The present specification has been amended herein at paragraph [0063] of U.S. Patent Application Publication No. 2004/0063122, published on April 1, 2004, corresponding to the present specification at page 11, line 35 to page 12, line 14 to correct a mistranslation of the parent priority document JP 210832/2002. Specifically, the phrase (e.g., 10 kb, or more preferably 30 kb or longer)" has been replaced with the phrase, "(e.g., 10 kb or longer, or more preferably 30 kb or longer)." Also, the phrase "(e.g., 10 kb or shorter, more preferably 2 kb or shorter)" has been replaced with, "(e.g., shorter than 10 kb, more preferably 2 kb or shorter)." These changes are not new matter as evidenced by: A) the attached Declaration of Toshihiro.

MORI under 37 C.F.R. § 1.132; and B) the fact that the parent priority document was incorporated by reference into the present disclosure in its entirety. (*See*, top of page 2 of July 18, 2003 transmittal).

### **Interview**

Applicants and Applicants' representatives thank the Examiners for extending the courtesy of an interview on or about August 28, 2007. During the interview, a proposed set of claim amendments was presented for the Examiners consideration. The proposed claim amendments discussed during the interview are substantially those reflected in the presently submitted claims listing. The obviousness and enablement issues were discussed. The substance of these discussions is substantially as reflected in the Interview Summary of record. It is noted that the present claims include the language "10 kb or longer" and that the Examiner has noted the discussion during the interview pointing out that this limitation is not disclosed or suggested by the cited references.

### **Rejections Under 35 U.S.C. § 103(a)**

#### Kitos et al. & Tsao et al.

Claims 1, 4, 5, 10, 16, 17 and 21 stand rejected as being unplantable over Kitos et al., *Biochemistry*, 12(25):5086-5091, 1973 (hereinafter, "Kitos et al.") in view of Tsao et al., U.S. Patent No. 4,090,022 (hereinafter, "Tsao et al."). (*See*, Office Action of June 5, 2007, at page 5, hereinafter, "Office Action"). Claims 4, 5 and 21 have been cancelled herein without prejudice

or disclaimer, thus obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as hereinafter set forth.

The Examiner states that Kito et al. do not disclose the limitation, "wherein the surface-saponification rate of the triacetylcellulose is 10 to 100% and the pore size of the porous film is 0.1  $\mu\text{m}$  to 10  $\mu\text{m}$ " recited in claim 1. However, the Examiner finds this limitation in the disclosure of Tsau et al. The Examiner states that it would have been obvious to one of ordinary skill in the art to combine the disclosures of Kito et al. and Tsao et al. because Tsao et al. disclose that the beads of Tsao et al. offer enhanced flow properties and because the method of Kito et al. is column-based and requires fluid flow.

Although Applicants do not agree that claim 1 is obvious in light of the disclosures of the combined references, to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to recite, in part, "A method for separating and purifying a nucleic acid having a length of 10 kb or longer from a nucleic acid sample solution, comprising: selecting a rate of surface saponification and pore size of a solid phase, said solid phase being a porous film of a surface-saponified triacetylcellulose; adsorbing a nucleic acid having a length of 10 kb or longer from a nucleic acid sample solution to said solid phase, wherein the solution contains nucleic acids of different lengths ..."

As highlighted in the comments concerning the Interview, above, Applicants believe that none of the cited references disclose or suggest isolation of nucleic acids having a length greater than 10 kb or longer using the presently claimed method steps.

This amendment is fully supported by the priority document JP 210832/2002, as explained in detail in the attached Declaration under 37 C.F.R. § 1.132 by Toshihiro MORI.

That is, the Declaration discloses that the present specification, at page 11, line 35 to page 12, line 14 recites a translation error. The specification as-filed provides the following incorrectly translated statement: "... (e.g., 10 kb, or more preferably 30 kb or longer) ..." which when properly translated actually means, "... (e.g., 10 kb or longer, more preferably 30 kb or longer) ...". Furthermore, the following second statement is also incorrectly translated in the specification: "... (e.g., 10 kb or shorter, more preferably 2 kb or shorter) ...". When properly translated, this second statement reads as follows: "... (e.g., shorter than 10 kb, more preferably 2 kb or shorter) ...". Thus, it is believed that the present amendment to claim 1 is fully supported by the original priority document as properly translated.

Since the cited references do not disclose or suggest each and every element of the presently claimed invention, it is believed that, at least as amended, claim 1 is not obvious in light of the cited references, even when their disclosures are considered in combination.

Although the Examiner provides rationale for the obviousness rejections of the dependent claims, none of the Examiner's comments directly addresses this new limitation. Therefore, it is believed that dependent claims 10, 16 and 17 are also not obvious in light of the combined disclosures of the cited references for, *inter alia*, depending from a non-obvious base claim, amended claim 1.

Reconsideration and withdrawal of the obviousness rejection of claims 1, 10, 16 and 17 are respectfully requested.

Kitos et al., Tsao et al. & Woodard et al.

Claims 12, 15 and 18 stand rejected as being unpatentable over Kitos et al. in view of Tsao et al., and further in view of Woodard et al., EP 0512767 (hereinafter, "Woodard et al."). (See, Office Action, at page 7).

Applicants' comments provided above, concerning the inadequate disclosures of Kitos et al. and Tsao et al., also may be effectively applied to the present rejection over these disclosures in combination with the disclosure of Woodard et al. because the disclosure of Woodard et al. does not cure the fatal defects of the disclosures of Kitos et al. and Tsao et al. That is, none of the cited references discloses all of the limitations recited in amended claim 1. Therefore, amended claim 1, and those claims depending therefrom, such as claims 12, 15 and 18, are believed to be non-obvious in light of the combined disclosures of the cited references.

Thus, reconsideration and withdrawal of the obviousness rejection of claims 12, 15 and 18 are respectfully requested.

Kitos et al., Tsao et al., Woodard et al. & Benjamin et al.

Claim 13 stands rejected as being unpatentable over Kitos et al. in view of Tsao et al. and Woodard et al. and in further view of Benjamin et al., U.S. Patent No. 5,695,946 (hereinafter, "Benjamin et al."). (See, Office Action, at page 9).

Applicants' comments provided above, concerning the inadequate disclosures of Kitos et al. and Tsao et al., also may be effectively applied to the present rejection over these disclosures in combination with the disclosure of Woodard et al. and Benjamin et al. because these disclosures also do not cure the fatal defects of the disclosures of Kitos et al. and Tsao et al. That

is, none of the cited references discloses all of the limitations recited in amended claim 1. Therefore, amended claim 1, and those claims depending therefrom, such as claim 13, are believed to be non-obvious in light of the combined disclosures of the cited references.

Reconsideration and withdrawal of the obviousness rejection of claim 13 are respectfully requested.

Kitos et al., Tsao et al., Woodard et al. & Heath

Claims 19 and 20 stand rejected as being unpatentable over Kitos et al. in view of Tsao et al. and Woodard et al., and further in view of Heath, WO 99/13976 (hereinafter, "Heath"). (See, Office Action, at page 10).

Applicants' comments provided above, concerning the inadequate disclosures of Kitos et al. and Tsao et al., also may be effectively applied to the present rejection over these disclosures in combination with the disclosures of Woodard et al. and Heath because these disclosures do not cure the fatal defects of the disclosures of Kitos et al. and Tsao et al. That is, none of the cited references discloses all of the limitations recited in amended claim 1. Therefore, amended claim 1, and those claims depending therefrom, such as claims 19 and 20, are believed to be non-obvious in light of the combined disclosures of the cited references.

For the foregoing reasons, reconsideration and withdrawal of the obviousness rejection of claims 19 and 20 are also respectfully requested.

**Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1, 4, 5, 10, 12, 13 and 15-22 remain rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement support in the specification. (*See*, Office Action, at page 11). Claims 4, 5, 21 and 22 have been cancelled herein without prejudice or disclaimer, thus obviating the rejections of these claims. Applicants traverse the rejections as to the remaining claims as hereinafter set forth.

The Examiner states that Applicants' arguments have been carefully considered but are not persuasive. The Examiner states that although Applicants' Declaration provides additional evidence of the range or separation allowed by the presently claimed invention, the Declaration is still unpersuasive.

The Examiner is respectfully reminded of the conversations of the Interview of August 28, 2007 wherein the Examiner stated the belief that there was enablement support in the present specification for separation and purification of nucleic acids having a length of 2 kb or less and/or nucleic acids having a length of 10 kb or more, either individually or in a mixture, using the saponified triacetylcellulose of the presently claimed invention.

Although Applicants do not agree that claim 1 is not enabled by the present specification, to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to recite, in part, "A method for separating and purifying a nucleic acid having a length of 10 kb or longer from a nucleic acid sample solution, comprising: selecting a rate of surface saponification and pore size of a solid phase, said solid phase being a porous film of a surface-saponified triacetylcellulose; adsorbing a nucleic acid having a length of 10 kb or longer from a nucleic acid sample solution to said solid phase, wherein the solution contains nucleic acids of different

lengths ...”

Applicants believe that the examples disclosed in the present specification as well as those provided in the previously submitted Declaration of Yumiko TAKESHITA fully enable one of ordinary skill in the art to make and use the invention, at least as recited in amended claim 1.

Since no independent reasoning is specifically provided for dependent claims 10, 12, 13 and 15-20, these claims are also believed to be enabled for, *inter alia*, depending from an enabled base claim, amended claim 1.

Reconsideration and withdrawal of the enablement rejection of claims 1, 10, 12, 13 and 15-20 are respectfully requested.



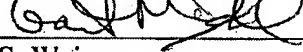
**CONCLUSION**

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Attachments: Declaration of Toshihiro MORI under 37 C.F.R. § 1.132 (3 pages)